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JOHANNSEN, DIANA B	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/880,732	BEE ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,9 and 59-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,9 and 59-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is responsive the Amendment and Response filed July 3, 2008. Claims 1 and 68 have been amended and claim 4 has been canceled. Claims 1-3, 5-6, 9, and 59-71 are now pending and under consideration. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow and in view of the new grounds of rejection that are set forth herein. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, second paragraph

The following are new grounds of rejection necessitated by applicants' amendments:

3. Claims 1-3, 5-6, 9, and 59-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 5-6, 9, and 59-71 are indefinite over the recitation of the limitation "contacting said allele of said pharmacogenetically relevant gene involved in drug metabolism in said sample with a capture probe (i) that is immobilized on a solid surface and (ii) that hybridizes to said nucleic acid molecule comprising said target nucleic acid sequence, wherein said nucleic acid molecule is not labeled with scattered-light detectable particles, and wherein said nucleic acid probe is labeled with scattered-light

detectable particles" in claim 1 (see step (d)). It is not clear how this limitation relates to the other method steps of the claim or to the objective of "detecting specifically an allele of a pharmacogenetically relevant gene involved in drug metabolism in a sample" (see preamble of claim 1). It is noted that canceled claim 4 was drawn to the "method of claim 1, further comprising contacting the sample with a capture probe (i) that is immobilized on a solid surface and (ii) that hybridizes to said nucleic acid molecule comprising said target nucleic acid sequence, wherein said nucleic acid molecule is not labeled with scattered-light detectable particles, and wherein said nucleic acid probe is labeled with scattered-light detectable particles." Thus, claim 4 limited the method of claim 1 to embodiments in which the nucleic acid molecule and the nucleic acid probe of step (a) had particular characteristics. However, present claim 1 states first that "either said nucleic acid probe or said nucleic acid molecule is labeled…." (step (a)) and then subsequently states that "said nucleic acid molecule is not labeled….and said nucleic acid probe is labeled" in step (d). It is not clear how or whether the recitations of step (d) relate to or further limit step (a) – how can the method on one hand require that the probe be labeled and the molecule not be labeled (as in step (d)), but also encompass the use of an unlabeled probe and labeled molecule (as recited in step (a))? Further, to the extent that step (d) may alternatively be drawn to, e.g., an additional method step employing an unlabeled molecule and a labeled probe, the language of the claim does not make clear how these reagents are employed in the "contacting" step (d), or how this "contacting" step relates to the objective of allele detection or to the other stated method steps. It is noted that step (c) states that light scattering is detected "as

indicative of the presence of said allele," suggesting that steps (a)-(c) achieve the stated objective of the claim. Thus, clarification is required with regard to how the "contacting" step (d) relates to detection and how it further limits the claim.

Claims 3 and 5-6 are also indefinite as a result of applicant's amendment of claim 1. Particularly, claims 3 and 5-6 require the use of an unlabeled probe and a labeled nucleic acid molecule, contradicting the requirements stated in new step (d) of claim 1. While the broader recitation of step (a) is noted, claim 1 is unclear for the reasons given above, and it is further unclear how the additional limitations of claims 3 and 5-6 further limit claim 1.

To the extent that claim 1 may be drawn to methods limited to the use of a labeled probe and unlabeled nucleic acid molecule (as recited in new step (d)), claims 9 and 49-67 are also unclear because claim 9 also references the labeling of the nucleic acid molecule, such that it is not clear how the claims further limit claim 1. Accordingly, it is noted that applicant's dependent claims should be amended so as to be consistent with any amendments made to independent claim 1.

Claims 68-69 recite the limitation "said contacting the sample" in lines 1-2 of each of the claims. There is insufficient antecedent basis for this limitation in claim 1, as claim 1 reference a step of contacting said allele…in said sample" but not a step of contacting "the sample." Thus, claims 68-69 should be amended so as to clarify how they further limit claim 1.

Claim Rejections – 35 USC § 103

4. In view of the cancellation of claim 4, the prior rejection of that claim under 35 USC 103 is now moot.

5. In view of applicant's amendment adding the limitations of (now canceled) claim 4 to the text of claim 1, the following rejections under 35 USC 103 are withdrawn:

a. The rejection of claims 1-3, 5-6, and 70-71 as being unpatentable over Cronin et al in view of Yguerabide et al;

b. The rejection of claims 9, 59-65 and 67 as being unpatentable over Cronin et al in view of Yguerabide et al and further in view of Yguerabide et al-II;

c. The rejection of claims 61, 64 and 66 as being unpatentable over Cronin et al in view of Yguerabide et al and Yguerabide et al-II and further in view of Haider et al.

6. Claims 1-3, 5-6, and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cronin et al in view of Yguerabide et al and Service. It is noted that a rejection under 35 USC 103 using the same combination of references previously applied to claims 4 (now canceled) and 68-69, and that **applicant's amendments to claim 1 necessitated the inclusion of claims 1-3, 5-6 and 70-71 in this rejection and the new grounds included herein.**

Cronin et al disclose array-based methods for differentiating alleles of CYP2D6 (see entire reference, particularly the Example at col 10, line 47-col 11, line 20). It is a property of CYP2D6 that it is a "pharmacogenetically relevant gene involved in drug

metabolism," as required by the claims; note, e.g., the text of claim 70, which states that "the pharmacogenetically relevant gene involved in drug metabolism encodes a cytochrome P450 protein," and the text of claim 71, which requires that "the pharmacogenetically relevant gene involved in drug metabolism is a member of the CYP2D family." Further, Cronin et al disclose target sequences unique to various CYP2D6 alleles, and (with particular regard to step (a) of claim 1) disclose contacting samples with arrays comprising probes that hybridize specifically to the target sequences (see again the Example at col 10-col 12; see also the definition of "probe" at col 2, lines 58-64). With further regard to step (a) of claim 1, Cronin et al disclose the labeling of target nucleic acid molecules with various types of labels (see, e.g., col 6, lines 12-35), and disclose general methods for detecting labeled molecules present on arrays (see col 7, line 55-col 9, line 55). Cronin et al also teach the use in their methods of light scattering labels including "gold, selenium, and titanium oxide" (see col 6, lines 27-29). However, Cronin et al teach that fluorescent labels are preferred for use in their methods (see col 3, lines 53-55), and Cronin et al do not disclose or exemplify the use of "scattered-light detectable particles" meeting the specific requirements of claim 1, step (a). Further, while Cronin et al teach the illumination of labels and detection of labeled molecules to achieve allele detection (see again col 7, line 55-col 9, line 55), Cronin et al do not specifically teach steps of illuminating scattered light detectable particles or detecting light scattered by said particles, as set forth in steps (b) and (c) of claim 1. Cronin et al also fail to teach an additional step of contacting with a capture probe as required by step (d).

Yguerabide et al disclose methods for the "ultrasensitive" detection of DNA target molecules, which methods use light scattering detectable particles in lieu of fluorescent labels and a "very simple and low-cost illumination system" employing white light (see entire reference, particularly page 137, right column, and page 154). Yguerabide et al also disclose that light scattering particles as employed in their methods are less susceptible to quenching and photodecomposition than are fluorescent labels (see page 155, right column). Yguerabide et al disclose the use of many different sizes and types of particles encompasses by the range set forth in claim 1, step (a); see, e.g., Tables 2, 3, and 4 at pages 150-151. Regarding claim 1, step (b), it is noted that Yguerabide et al disclose that light scattered during their methods can be detected by the human eye without electronic amplification "at magnifications as low as 40X total magnification" (see page 140, left column).

In view of the teachings of Yguerabide et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cronin et al so as to have employed therein as labels the scattered-light detectable particles of Yguerabide et al, and to have employed therein the illumination technique of Yguerabide et al, and thereby further to have practiced a method in which light scattering (rather than, e.g., fluorescence) is detected as an indicator of the presence of a particular allele. An ordinary artisan would have been motivated to have made such modifications to have achieved the advantages of ultrasensitive, simple and low cost detection, as taught by Yguerabide et al, and/or for the advantage of alleviating any problems related to quenching and/or

photodecomposition occurring with the use of fluorescent labels, as suggested by Yguerabide et al.

It is noted that the instant claims require a further step (d) of "contacting said allele of said pharmacogenetically relevant gene involved in drug metabolism in said sample with a capture probe (i) that is immobilized on a solid surface and (ii) that hybridizes to said nucleic acid molecule comprising said target nucleic acid sequence, wherein said nucleic acid molecule is not labeled with scattered-light detectable particles, and wherein said nucleic acid probe is labeled with scattered-light detectable particles." Thus, steps (a)-(c) encompass the use of unlabeled probes and a labeled target nucleic acid molecule (see text of step (a)) and achieve the objective of detection "as indicative of the presence of" the allele in said sample (see text of step (c)); it is again noted that it is not clear how the recitations of step (d) relate to and further limit steps (a)-(c), for the reasons given above. While the limitations of the claim are not clear, it appears that the claim may encompass methods in which the probe of step (a) is labeled and the molecule of step (a) unlabeled (i.e., such that only some embodiments suggested by the text of step (a) are intended to be excluded by the recitations of step (d); it also appears that the claims may encompass methods including a separate, additional step employing a capture probe, a target molecule that is not labeled with scattered-light detectable particles, and a nucleic acid probe that is so labeled. Cronin et al and Yguerabide et al do not teach methods comprising the use of probes labeled with scatter-light detectable particles, target nucleic acids that are not

so labeled, and an immobilized capture probe, wherein the capture probe is also contacted with the "allele" in the sample.

Service discloses both methods in which labeled target nucleic acids are hybridized to arrays of unlabeled oligonucleotides (see page 398, left and center columns), as well as an alternative array-based method for detecting specific sequences in which unlabeled target nucleic acid is hybridized to (i.e., "captured") by array-immobilized, unlabeled oligonucleotide probes, and in which a third population of nucleic acids identified as "tagged" oligos are included in hybridization reactions to achieve determination of the sequence present in the target nucleic acid (see page 398, center column). To the extent that the claims may encompass methods in which the probe of step (a) is labeled, the molecule of step (a) is unlabeled, and a separate immobilized capture probe is employed in allele capture, modification of the method suggested by Cronin et al in view of Yguerabide et al so as to employ unlabeled target nucleic acid in combination with a population of probes tagged with scattered-light detectable particles would have been obvious to one of ordinary skill in the art at the time the invention was made because it constitutes the mere substitution of one prior art array based detection method (as taught by Service) for another to achieve the predictable result of detecting the allele present in a sample. Alternatively, to the extent that the claims are drawn to methods in which an additional step of allele-capture is practiced as set forth in step (d), an ordinary artisan would have been motivated to have practiced such an additional step for the advantage of rapidly confirming the allele

detection achieved by the practice of the initial method steps (a)-(c) suggested by Cronin et al in view of Yguerabide et al.

With further regard to claim 2, it is noted that Cronin et al disclose the amplification of target nucleic acids prior to hybridization with probes (see, e.g., col 6, lines 2-13).

Regarding claim 3, 5, and 6, it is again noted that Cronin et al disclose labeled target molecules and arrays of unlabeled immobilized probes that capture the target molecules via hybridization, as discussed above (see entire reference, particularly col 5, line 59-col 7, line 54; col 9, lines 57-62).

With further regard to claims 5-6 and 68-71, it is again noted that Cronin et al disclose the differentiation of CYP2D6 alleles using different specific probes on an array (see the Example at col 10, line 47-col 11, line 20).

With regard to the prior rejection of claims 68-69 as being unpatentable over Cronin et al in view of Yguerabide et al and Service, it is noted that the reply traverses the rejection on the grounds that "Service relates to microchip arrays" and on the grounds that the references do not "disclose or suggest contacting the sample with a capture probe (i) that is immobilized on a solid surface and (ii) that hybridizes to said nucleic acid molecule comprising said target nucleic acid sequence, wherein said nucleic acid molecule is not labeled with scattered-light detectable particles, and wherein said nucleic acid probe is labeled with scattered-light detectable particles." However, as the references do suggest methods meeting all the requirements of the claims for the reasons given above, this argument is not persuasive. It is noted that

paragraph 23 of the specification teaches that the term "capture probe" refers to "an oligonucleotide-containing molecule that hybridizes to a target molecule and allows the target molecule to be removed or otherwise separated from bulk sample;" the capture probes suggested by the references have these properties and are therefore encompassed by the claims.

The following are new grounds of rejection necessitated by applicants' amendments:

7. Claims 9, 59-65, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cronin et al in view of Yguerabide et al and Service, as applied to claims 1-3, 5-6, and 68-71, above, and further in view of Yguerabide et al-II.

Regarding claim 9 and claims dependent therefrom, it is noted that Cronin et al disclose labeling target nucleic acid during amplification, and disclose the incorporation of various fluorescent labels (see col 6, lines 12-26). However, while Cronin et al, Yguerabide et al and Service suggest the use of scattered-light detectable particles as labels (as discussed above), the references do not teach labeling "by incorporating a moiety that provides an attachment site and/or a cleavage site" (see text of claim 9), and further do not teach such labeling using any of the methods of claim 59. Further, the references do not teach embodiments wherein the incorporated moiety is "a modified nucleotide" (see claim 60), or a "hapten-derivatized nucleotide or bromodeoxyuridine" (claim 61), and do not teach the types of labels or "attaching" procedures of claims 62-65. The references also fail to teach labeling as required by

claim 67, due to the failure to teach "an attachment site and/or a cleavage site" as set forth in claim 9 (from which claim 67 depends).

Like Yguerabide et al, Yguerabide et al-II disclose the use of scattered-light detectable particles as labels in sensitive detection methods employing white light illumination (see entire reference, particularly pages 164-165). Yguerabide et al-II disclose the incorporation of biotin into DNA molecules, and the attachment of scattered-light detectable particles coated with streptavidin, or coated with antibodies against any DNA-incorporated antigen, to such DNA (see page 174, right column). Yguerabide et al-II therefore suggest labeling DNA by incorporating into the DNA nucleotides derivatived with the hapten biotin, and the attachment of either streptavidin-coated or antibody-coated detectable particles to such DNA, as set forth in the claims. It is noted that the biotin serves as an "attachment site" for streptavidin or for the specific antibody, such that the requirements of claim 9 are met. In view of the teachings of Yguerabide et al-II, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cronin et al in view of Yguerabide et al and Service so as to have prepared target nucleic acids labeled with scattered-light detectable particles by incorporating into the nucleic acids (by PCR or any other well known method) biotin derivatized nucleotides, and by attaching to said nucleotides detectable particles labeled with either streptavidin or anti-biotin antibodies, as taught by Yguerabide et al-II. Such a modification of the method suggested by Cronin et al in view of Yguerabide et al and Service would have been obvious to one of ordinary skill in the art because it constitutes the mere

substitution of one type of prior art labeling method with another to achieve the predictable result of preparing labeled target nucleic acids Further, an ordinary artisan would have been motivated to have made such a modification in order to have prepared nucleic acids labeled with the type of label having the advantages taught by Yguerabide et al (rather than to have, e.g., experimented with various methods of preparing such molecules) for the advantage of more rapidly and efficiently preparing the nucleic acids needed for the methods suggested by Cronin et al in view of Yguerabide et al and Service.

With further regard to claim 67, it is noted that Cronin et al disclose the use in amplification of primers that "flank the borders of a target polynucleotide of interest" (see col 6, lines 7-9), and that Cronin et al disclose and exemplify the detection of various alleles of the CYP2D6 gene (see the example at col 10-col 12). Although Cronin et al do not disclose the labeling of CYP2D6 target nucleic acids using primers specific for the CYP2D6 gene, in view of Cronin et al's own teachings it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have employed such primers in the method suggested by Cronin et al in view of Yguerabide et al, Service and Yguerabide et al-II in order to have achieved the predictable result of preparing appropriate, labeled target nucleic acids for use in the method.

8. Claims 61, 64, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cronin et al in view of Yguerabide et al, Service and Yguerabide et

al-II as applied to claims 9, 59-65, and 67, above, and further in view of Haider et al (Experimental Cell Research 234:498-506 [1997]).

This rejection applies to claims 61 and 64 to the extent that they may be limited to methods requiring bromodeoxyuridine and particles derivatized with anti-bromodeoxyuridine.

With regard to the requirement in claim 66 that "said target nucleotide sequence is fragmented prior to hybridization with said nucleic acid probe," it is noted that the primary reference Cronin et al teaches that "The target is preferably fragmented before application to the chip to reduce or eliminate the formation of secondary structures in the target," and therefore discloses such a step and provides motivation to include it to achieve the advantages noted by Cronin et al. However, Cronin et al, Yguerabide et al, Service and Yguerabide et al-II do not teach the incorporation of bromodeoxyuridine into target nucleic acids, or the use of particles derivatived with anti-bromodeoxyuridine, as required by the claims.

Haider et al teaches that biotin-labeled nucleotides "are essentially limited to *in vitro* studies because of the poor penetrability of these molecules through the plasma membrane of live cells" (see entire reference, particularly page 498, right column) whereas BrdU labeled nucleotides may be successful employed both *in vivo* and *in vitro* (see page 499, left column). Haider et al also disclose the attachment of beads derivatized with anti-BrdU to nucleic acids containing BrdU (see page 499, left column and 500, left column), and teach that such nucleic acids may be successfully prepared by PCR and isolated using anti-BrdU coated beads (see page 499, left column, and

page 500). In view of the teachings of Haider et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cronin et al, Yguerabide et al, Service and Yguerabide et al-II so as to have employed therein BrdU in lieu of biotin and scattered-light detectable particles labeled with anti-BrdU in lieu of such particles labeled with streptavidin or anti-biotin. Such a modification would have been obvious to one of ordinary skill in the art because it constitutes the mere substitution of one type of prior art labeling method with another to achieve the predictable result of preparing labeled target nucleic acids Further, an ordinary artisan would have been motivated to have made such a modification in order to have prepared nucleic acids having the advantages taught by Haider et al, specifically, for example, nucleic acids that could be prepared *in vivo* rather than *in vitro* in such instances when such a preparation method was more convenient for a practitioner.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634

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